

## REMARKS

Applicants thank the Examiner for the interview conducted December 12, 2006, and present in this Reply remarks discussed in that interview which address the utility of the claimed invention.

### Rejections under 35 U.S.C. § § 101 and 112, first paragraphs

In connection with the rejection of claims 1-8 and 15 under 35 U.S.C. § 101 on the ground that “the claimed invention lacks patentable utility”, applicants submit the following additional remarks.

Applicants’ specification clearly discloses readily apparent utilities for the invention as claimed, which are based, in part, on applicants’ identification of a novel trypsin-family serine protease. In particular, applicants’ specification at page 36 (lines 13-16) teaches the identification of a protease, designated “Tespec PRO-1” (Testis specific expressed serine proteinase-1), and, at page 36 (lines 18-21), the nucleotide (SEQ ID NO:1) and the amino acid sequence (SEQ ID NO:2) of a Tespec PRO-1 protease are disclosed. Using standard sequence analysis, applicants further teach that the Tespec PRO-1 amino acid sequence included two types of trypsin-family serine protease signature motifs: “Trypsin-Ser” and “Trypsin-His”. Here applicants’ specification at page 36 (lines 25-27) states:

Based on the analytical search of the GCG, the amino acid sequence was proved to contain two types of trypsin-family serine protease motifs, “Trypsin-His (PROSITE PS00134)” and “Trypsin-Ser (PROSITE

PS00135)”.

Furthermore, applicants’ specification at page 36 (lines 28-32) teaches that PROSITE, which consists of documentation entries describing protein domains, families and functional sites as well as associated patterns and profiles to identify them, stated that

PROSITE indicates “*if a protein includes both the serine and histidine active site signatures, the probability of it being a trypsin family serine protease is 100%*” (Brenner, S., 1988, Nature, 334: 528-530; Rawlings, N. D. and Barrett, A. J. (1994) Meth. Enzymol., 244: 19-61)(emphasis added.).

Applicants’ specification also makes clear that, in view of the PROSITE teaching, Tespec PRO-1 is a trypsin-family serine protease.<sup>1</sup> The specification, at page 36 (lines 32-33) reads:

“Tespec PRO-1” therefore can be regarded as a trypsin-family serine protease.

Thus, applicants’ specification demonstrates several important facts about the Tespec PRO-1 protease that are the basis for the utilities of applicants’ claimed invention.

---

<sup>1</sup> In connection with PROSITE, applicants enclose, as Appendix A, PROSITE documentation PDOC00124 (<http://www.expasy.org/cgi-bin/prosite-search-ac?PDOC00124>, last visited December 14, 2006). Applicants point out that, although updated May 2002, this PROSITE documentation makes clear that, as stated in applicants’ specification, “*if a protein includes both the serine and histidine active site signatures, the probability of it being a trypsin family serine protease is 100% (emphasis added)*”. Furthermore, as noted in applicants’ specification, this PROSITE documentation teaches the serine (PS00135) and histidine (PS00134) active sites.

In sum, given applicants' explicit teaching that Tespec PRO-1 includes both the serine and histidine active site signatures and the fact that skilled workers recognized that, at the time the application was filed, *"if a protein includes both the serine and histidine active site signatures, the probability of it being a trypsin family serine protease is 100%"*, then there can be little question that compositions falling within the scope of applicants' claims have a readily apparent utility as trypsin serine proteases or DNA molecules encoding such proteases. Accordingly, because the utility of applicants' claimed invention is specific, substantial, and credible, the related rejections under 35 U.S.C. § 101 and § 112, first paragraph should therefore be withdrawn.

#### Rejoinder of Withdrawn Claims

As applicant believes that all claims (1-8 and 15 )are in condition for allowance, applicant respectfully requests that withdrawn claims 9 and 11, which are directed to methods of using the products encompassed by claims 1 and 2, be rejoined, in accordance with M.P.E.P. § 821.04.

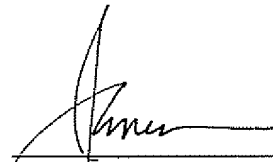
CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 10 Jan 2007



---

James D. DeCamp, Ph.D.  
Reg. No. 43,580

Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045